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NATH & ASSOCIATES 112 South West Street Alexandria, VA 22314			EXAMINER CARTER, KENDRA D	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/506,407	<b>Applicant(s)</b> FRANCHI ET AL.	
	<b>Examiner</b> Kendra D. Carter	<b>Art Unit</b> 1617	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 2 July 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 31-84 is/are pending in the application.
- 4a) Of the above claim(s) 36-39, 45-66, 70-73 and 80-83 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31-35, 40-44, 67-69, 74-79 and 84 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |  |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                                  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____   |

### **DETAILED ACTION**

The Examiner acknowledges the applicant's remarks and arguments of July 2, 2007 made to the office action filed February 1, 2007. Claims 31-84 are pending. Claim 59 is amended and claims 36-39, 45-66, 70-73 and 80-83 are withdrawn.

The Examiner thanks Attorney Harkins for faxing the missing page in the response filed July 2, 2007. The Examiner has submitted it for the records to be scanned.

For the reasons in the previous office action and below, the Applicant's arguments of the 35 U.S.C. 103(a) rejection of claims 67, 69 and 74-76 as being obvious over Jackson et al. (U.S. 5,578,641), in view of Bombardelli et al (U.S. 5,679,358), were found not persuasive, and thus upheld.

For the reasons in the previous office action and below, the Applicant's arguments of the 35 U.S.C. 103(a) rejection of claim 68 as being obvious over Jackson et al. (U.S. 5,578,641), in view of Bombardelli et al. (U.S. 5,679,358) as applied to claims 67, 69 and 74-76 above, and further in view of Streekstra et al. (WO 00/53568) to were found not persuasive, and thus upheld.

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For the reasons in the previous office action and below, the Applicant's arguments of the 35 U.S.C. 103(a) rejection of claim 77 as being obvious over Jackson et al. (U.S. 5,578,641), in view of Bombardelli et al. (U.S. 5,679,358) as applied to claims 67, 69 and 74-76 above, and further in view of Andre et al. (U.S. 5,709,864), were found not persuasive, and thus upheld.

For the reasons in the previous office action and below, the Applicant's arguments of the 35 U.S.C. 103(a) rejection of claims 67, 69, 74 and 78-79 as being obvious over Jackson et al. (U.S. 5,578,641), in view of Andre et al. (U.S. 5,709,864), were found not persuasive, and thus upheld.

For the reasons in the previous office action and below, the Applicant's arguments of the 35 U.S.C. 103(a) rejection of claims 31-32, 34-35, 40-42 and 84 as being obvious over Bombardelli et al. (U.S. 5,679,358) in view of Jackson et al. (U.S. 5,578,641), were found not persuasive, and thus upheld.

For the reasons in the previous office action and below, the Applicant's arguments of the 35 U.S.C. 103(a) rejection of claim 33 as being obvious over Bombardelli et al. (U.S. 5,679,358) in view of Jackson et al. (U.S. 5,578,641) as applied to claims 31-32, 34-35, 40-42 and 84 above, and further in view of Streekstra et al. (WO 00/53568), to were found not persuasive, and thus upheld.

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For the reasons in the previous office action and below, the Applicant's arguments of the 35 U.S.C. 103(a) rejection of claims 43-44 as being obvious over Bombardelli et al. (U.S. 5,679,358) in view of Jackson et al. (U.S. 5,578,641) as applied to claims 31-32, 34-35, 40-42 and 84 above, and further in view of Andre et al. (U.S. 5,709,864), to were found not persuasive, and thus upheld.

The restriction requirement is also maintained because currently all rejections are upheld.

Due to no new substantial amendments to the claims and that all previous rejections are upheld, the previous rejections made are restated below.

The Applicant's arguments are addressed below.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

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Patentability shall not be negated by the manner in which the invention was made.

**(1) Claims 67, 69 and 74-76 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 5,578,641 to Jackson et al. issued November 26, 1996, in view of U.S. Patent No. 5,679,358 to Bombardelli et al, issued October 21, 1997.**

Jackson et al. teaches a composition for topical application to the skin comprising from 0.0001 to 10% by weight of one or more ceramide pathway intermediates (see abstract, in particular.) Jackson et al. teaches that the composition can be applied to human skin for the eradication or reversal of skin aging, removal of rough or dry skin and improving the loss of elasticity and flexibility of skin, among others (see column 2, lines 50-60, in particular.) Jackson teaches that a preferred ceramide pathway intermediate is phytosphingosine (see column 4, lines 14-20, in particular.)

Jackson et al. also does not specifically teach providing a composition with a lipolytic agent, as recited in claim 67. However, Jackson et al. does teach that further cosmetic adjuvants can be provided in the composition (see column 11, line 30 through column 1, line 15, in particular.)

Bombardelli et al. teaches a composition comprising esculoside in combination with an adenylate cyclase stimulator (lipolytic agent) in topical formulations (see

abstract, in particular.) Bombardelli et al. teaches that the ingredient can act to improve skin early aging, particularly face and neck skin (see column 3, lines 1-12, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the ingredients including the adenylate cyclase stimulator of Bombardelli et al. in the composition of Jackson et al, because Jackson et al. teaches applying a composition to reduce wrinkles associated with skin aging, and teaches the composition can have other adjuvants, and Bombardelli et al. teaches that ingredients including an adenylate cyclase stimulator act to improve skin aging. Thus, one of ordinary skill in the art would have been motivated to provide an adjuvant comprising the adenylate cyclase stimulator-containing ingredients of Bombardelli et al. in the wrinkle-treating composition of Jackson et al, with the expectation of providing a composition that treats signs of the early aging of skin such as skin wrinkles. Note it is considered that "[I]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980.) Accordingly, claim 67 is considered to be obvious over the references.

It is respectfully pointed out that a recitation of an intended use of the claimed invention must result in a structural difference between the claimed invention and the

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prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963.) Thus the intended use recited in claim 67, namely that the cosmetic composition is "notably intended for reducing subcutaneous excess fat," is not afforded patentable weight.

Regarding claim 69, Jackson et al. teaches that the composition for topical application to the skin can comprise from 0.0001 to 10% by weight of one or more ceramide pathway intermediates such as phytosphingosine, as discussed above, and thus teaches an amount that meets and/or overlaps with the amount recited in the claim. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of phytosphingosine provided in the composition, according to the guidance provided by Jackson et al, to provide a composition having desired properties, such as desired skin treatment properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)



Regarding claim 74, Bombardelli et al. teaches providing an adenylate cyclase stimulator (activating agent), as discussed for claim 67 above. Regarding claim 75, Bombardelli et al. teaches that the adenylate cyclase stimulator can be forskolin (see abstract, in particular.) Regarding claim 76, Bombardelli et al. teaches that the adenylate cyclase stimulator can comprise from about 0.1 to 1% of the composition (see column 1, lines 40-65, in particular), and thus teaches an amount that meets the limitations of the claims. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of adenylate cyclase stimulator provided in the composition, according to the guidance provided by Bombardelli et al. to provide a composition having desired sin treatment effects. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

**(2) Claim 68 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,578,641 to Jackson et al, issued November 26, 1996, in view of U.S. Patent No. 5,679,358 to Bombardelli et al, issued October 21, 1997, and as applied to claims 67, 69 and 74-76 above, and further in view of WO 00/53568 to Streekstra et al, published September 14, 2000.**

Jackson et al and Bombardelli et al. are applied as discussed for claims 67, 69 and 74-76 above, and teach applying a composition to skin comprising a ceramide pathway intermediate, such as phytosphingosine, to provide an antiaging effect, and also teach that the same parts of the body in need of an anti-aging effect can be those in need of a slimming effect. Jackson et al. and Bombardelli et al. also teach that the composition can comprise an adenylate cyclase inhibitor. Jackson et al. furthermore teaches that the composition can be provided with water as a vehicle (see column 6, lines 15-20, in particular.)

Jackson et al. and Bombardelli et al. do not specifically teach providing phytosphingosine in the form of phytosphingosine hydrochloride, as recited in claim 68.

Streekstra et al. teaches that forming the salt of sphingoid bases, such as the hydrochloric acid salt phytosphingosine, provides a sphingoid compound having better solubility in topical formulations containing water than their free base counterparts (see page 2, lines 1-35, and page 3, lines 15-17, and Example 3, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the phytosphingosine hydrochloride of Streekstra et al. in the phytosphingosine-containing composition of Jackson et al, with the expectation of providing a phytosphingosine form having improved solubility in the water-containing vehicle of Jackson et al.

**(3) Claim 77 is rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 5,578,641 to Jackson et al. issued November 26, 1996 in view of U.S. Patent No. 5,679,358 to Bombardelli et al, issued October 21, 1997, as applied to claims 67, 69 and 74-76 above, and further in view of U.S. Patent No. 5,709,864 to Andre et al, issued January 20, 1998.**

Jackson et al. and Bombardelli et al. are applied as discussed for claims 67, 69 and 74-76 above, and teach a composition comprising phytosphingosine and an adenylate cyclase stimulator, and a method for applying the composition to the skin. Bombardelli et al. furthermore teaches that the adenylate cyclase stimulator can be forskolin (see abstract, in particular.)

Jackson et al. and Bombardelli et al. do not specifically teach providing an adenylate cyclase stimulator that is an extract of *Coleus forskohlii* or *Plectranthus barbatus*, as recited in claim 77.

Andre et al. teaches that an extract of *Coleus forskohlii* contains forskoline (forskolin) and is known for its activity in stimulating adenylate cyclase (see column 5, lines 60-68, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was known would have found it obvious to provide the *Coleus forskohlii* extract of Andre et al. in the phytosphingosine and adenylate cyclase stimulator composition and method of Jackson et al. and Bombardelli et al, because Jackson et al. and Bombardelli et al. teach that an adenylate cyclase stimulator such as forskolin can be provided, and Andre et al. teaches that an extract of *Coleus forskohlii* provides the forskolin adenylate cyclase stimulator. Thus, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the extract of Andre et al. in the composition and/or method of Jackson et al. and Bombardelli et al, with the expectation of providing a suitable forskolin containing adenylate cyclase stimulator in the composition. Accordingly, claim 77 is obvious over the teachings of Jackson et al, Bombardelli et al. and Andre et al.

**(4) Claims 67, 69, 74 and 78-79 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 5,578,641 to Jackson et al. issued November 26, 1996 in view of U.S. Patent No. 5,709,864 to Andre et al, issued January 20, 1998.**

Jackson et al. is applied as discussed above, and teaches a method for application to the skin of a formulation comprising phytosphingosine. Jackson et al. further teaches that the composition can be used in the treatment of skin to reduce or delay the development of wrinkles associated with advancing age or with sun-induced aging (see column 2, lines 10-20, in particular.) Jackson et al. also teaches that further

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cosmetic adjuncts can be provided in the composition (see column 11, line 30 through column 1, line 15, in particular.)

Jackson et al. does not specifically teach providing a composition with a lipolytic agent as recited in claims 67, 69 and 74-79.

Andre et al. teaches that an extract of Tephrosia purpurea provides powerful stimulation activity of the enzyme adenylate cyclase (lipolytic agent) (see column 1, lines 30-45, in particular.) Andre et al. teaches that the extract can be provided in a cosmetic composition to provide anti-aging effects (see abstract, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the extract of Andre et al. in the composition of Jackson et al, because Jackson et al. teaches applying a composition to reduce wrinkles associated with skin aging, and teaches the composition can have other adjuvants, and Andre et al. teaches that an extract that acts as an adenylate cyclase has anti-aging effects in cosmetic compositions. Thus, one of ordinary skill in the art would have been motivated to provide an adjuvant comprising the extract of Andre et al. in the wrinkle-treating composition of Jackson et al. and applying to skin, with the expectation of providing a composition that treats aging of skin such as wrinkles and has anti-aging effects. Note it is considered that "[I]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same

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purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980.)

Regarding the composition of claim 67, it is noted that Jackson et al. teaches a composition for reducing wrinkles associated with ageing, whereas Andre et al. teaches that a composition with an extract that is an adenylate cyclase enzyme stimulator (activating agent) can provide anti-aging effects. Jackson et al. also teaches that the composition can comprise a cosmetically acceptable vehicle (see column 5, lines 60-68, in particular), as recited in the claim. Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the adenylate cyclase activating extract of Andre et al. in the wrinkle-treating composition of Jackson et al., with the expectation of providing a composition that treats aging of skin such as skin wrinkles and has anti-aging effects. Note it is considered that "[I]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980.) Accordingly, the composition of claim 67 is also obvious over Jackson et al. and Andre et al.

It is respectfully pointed out that a recitation of an intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963.) Thus the intended use recited in claim 67, namely that the cosmetic composition is "notably intended for reducing subcutaneous excess fat," is not afforded patentable weight.

Regarding claim 74, Andre et al. teaches that the extract is an adenylate cyclase enzyme activator.

Regarding claim 69, Jackson et al. teaches a cosmetic composition comprising 0.1% phytosphingosine (see Example 1, in particular), and thus teaches providing the weight percentage recited in the claim. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of phytosphingosine provided in the composition, according to the guidance provided by Jackson et al, to provide a composition having desired skin treatment properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or

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workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claims 78-79, Andre et al. teaches that the extract can be from *Tephrosia purpurea*, and also teaches that the extract can be provided in a topical composition in an amount between 0.01 to 5% by weight (see column 1, lines 45-55 and column 2, lines 20-25, in particular), which meets the range limitation recited in claim 79. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of extract provided in the composition, according to the guidance provided by Andre et al, to provide a composition having desired treatment properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

**(5) Claims 31-32, 34-35, 40-42 and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,679,358 to Bombardelli et al, issued October 21, 1997, in view of U.S. Patent No. 5,578,641 to Jackson et al, issued November 26, 1996.**

Bombardelli et al. teaches the topical application of a composition comprising esculoside in combination with an adenylate cyclase stimulator (lipolytic agent) (see



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abstract, in particular.) Bombardelli et al. teaches that the composition is topically applied for treatment of cellulitis or unestetisms connected with a deposit of superfluous fat (see abstract in particular.) Thus, it is considered that Bombardelli et al. teaches a method of application of a composition on the part or parts of the body presenting subcutaneous fat, as recited in claims 31 and 32, and also teaches the composition having a lipolytic agent that is an adenylate cyclase enzyme activating agent, as in claims 35 and 40. Bombardelli et al. also teaches that the composition can act to improve skin early aging, particularly face and neck skin (see column 3, lines 1-12, in particular.)

Bombardelli et al. does not specifically teach providing a slimming effective amount of a phytosphingosine compound, as recited in claim 31.

Jackson et al. teaches a composition for topical application to the skin comprising from 0.0001 to 10% by weight of one or more ceramide pathway intermediates (see abstract, in particular.) Jackson et al. teaches that the composition can be applied to human skin for the eradication or reversal of skin aging, removal of rough or dry skin and improving the loss of elasticity and flexibility of skin, among others (see column 2, lines 50-60, in particular.) Jackson teaches that a preferred ceramide pathway intermediate is phytosphingosine (see column 4, lines 14-20, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the phytosphingosine of Jackson et al. in the cellulitis and unesthetism treatment composition and method of Bombardelli et al, because Bombardelli et al. teaches treating cellulites and unesthetisms, such as those associated with skin aging, via topical application of the compositions, whereas Jackson et al. teaches that ceramide pathway intermediates such as phytosphingosine can be topically applied to reduce wrinkles associated with skin aging. Thus, one of ordinary skill in the art would have been motivated to provide the skin-aging and wrinkle treating phytosphingosine ingredient of Jackson et al, in the cellulites and skin aging unesthetism treating composition and method of Bombardelli et al, with the expectation of providing a composition and method that treats skin unesthetisms such as cellulitis and other signs of the early aging of skin such as skin wrinkles. Note it is considered that "[I]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980.)

It is furthermore noted that the 0.0001 to 10% by weight amount of ceramide pathway intermediate taught by Jackson et al. is considered to meet and/or overlap with the "slimming effective amount" as recited in claims 31 and 34, and an amount that can stimulate the synthesis of leptin by adipocytes, as in claim 84. Furthermore, it is

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considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of phytosphingosine provided in the composition, according to the guidance provided by Jackson et al. and Bombardelli et al, to provide a composition having desired properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.) Accordingly, claim 31 is considered to be obvious over the teachings of Bombardelli et al. and Jackson et al.

Regarding claim 41, Bombardelli et al. teaches that the adenylate cyclase stimulator can be forskolin (see abstract, in particular.) Regarding claim 42, Bombardelli et al. teaches that the adenylate cyclase stimulator can comprise from about 0.1 to 1% of the composition (see column 1, lines 40-65, in particular), and thus teaches an amount that meets the limitations of the claims. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of adenylate cyclase stimulator provided in the composition, according to the guidance provided by Bombardelli et al. to provide a composition having desired skin treatment effects. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

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**(6) Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,679,358 to Bombardelli et al, issued October 21, 1997, in view of U.S. Patent No. 5,578,641 to Jackson et al, issued November 26, 1996, as applied to claims 31-32, 34-35, 40-42 and 84 above, and further in view of WO 00/53568 to Streekstra et al, published September 14, 2000.**

Bombardelli et al. and Jackson et al. are applied as discussed for claims 31-32, 34-35, 40-42 and 84 above, and teach applying a composition to skin comprising a ceramide pathway intermediate, such as phytosphingosine, and an adenylate cyclase inhibitor, to treat cellulites and other unesthetisms associated with aging, such a skin wrinkles. Bombardelli et al. furthermore teaches that the composition can be provided with a pharmaceutically acceptable carrier and exemplifies compositions containing water as a carrier (see column 1, lines 58-62, and Examples I-III and V, in particular.)

Bombardelli et al. and Jackson et al. do not specifically teach providing phytosphingosine in the form of phytosphingosine hydrochloride, as recited in claim 33.

Streekstra et al. teaches that forming the salt of sphingoid bases, such as the hydrochloric acid salt phytosphingosine, provides a sphingoid compound having better solubility in topical formulations containing water than their free base counterparts (see page 2, lines 1-35, and page 3, lines 15-17, and Example 3, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the phytosphingosine hydrochloride of Streekstra et al. in the phytosphingosine-containing composition of Bombardelli et al. and Jackson et al, with the expectation of providing a phytosphingosine form having improved solubility in a water-containing vehicle of Bombardelli et al. and Jackson et al.

**(7) Claims 43-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,679,358 to Bombardelli et al, issued October 21, 1997, in view of U.S. Patent No. 5,578,641 to Jackson et al, issued November 26, 1996, as applied to claims 31-32, 34-35, 40-42 and 84 above, in view of U.S. Patent No. 5,709,864 to Andre et al, issued January 20, 1998.**

Bombardelli et al. and Jackson et al. are applied as discussed for claims 31-32, 34-35, 40-42 and 84 above, and teach applying a composition to skin comprising a ceramide pathway intermediate, such as phytosphingosine, and an adenylate cyclase inhibitor, to treat cellulites and other unesthetisms associated with aging, such a skin wrinkles. Bombardelli et al. furthermore teaches that the adenylate cyclase stimulator can be forskolin (see abstract, in particular.)

Bombardelli et al. and Jackson et al. and do not specifically teach providing an adenylate cyclase stimulator that is an extract of *Coleus forskohlii* or *Plectranthus*

barbatus, as recited in claim 43, or that is an extract of the plant *Tephrosia purpurea*, as recited in claim 44.

Andre et al. teaches that an extract of *Coleus forskohlii* contains forskoline (forskolin) and is known for its activity in stimulating adenylate cyclase (see column 5, lines 60-68, in particular.) Andre et al. also teaches that an extract of *Tephrosia purpurea* provides powerful stimulation activity of the enzyme adenylate cyclase (lipolytic agent) (see column 1, lines 30-45, in particular.) Andre et al. teaches that the extracts can be provided in a cosmetic composition to provide anti-aging effects (see abstract, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was known would have found it obvious to provide the *Coleus forskohlii* extract or *Tephrosia purpurea* extracts of Andre et al. in the phytosphingosine and adenylate cyclase stimulator composition and method of Bombardelli et al. and Jackson et al, because Bombardelli et al. and Jackson et al. teach that an adenylate cyclase stimulator such as forskolin can be provided, and Andre et al. teaches that an extract of *Coleus forskohlii* provides the forskolin adenylate cyclase stimulator, and that *Tephrosia pupurea* extract also provides an adenylate cyclase activating agent. Thus, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the extracts of Andre et al. in the composition and/or method of Bombardelli et al. and Jackson et al, with the expectation of providing a suitable forskolin containing adenylate

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cyclase stimulator in the composition and method. Accordingly, claims 43-44 are obvious over the teachings of Bombardelli et al, Jackson et al, and Andre et al.

### ***Response to Arguments***

Applicant's arguments filed have been fully considered but they are not persuasive.

Claims 67, 69 and 74-76 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 5,578,641 to Jackson et al. issued November 26, 1996, in view of U.S. Patent No. 5,679,358 to Bombardelli et al, issued October 21, 1997.

The Applicant argues that each and every limitation of the presently claimed invention is not taught or suggested in the combination references. Jackson et al. does not teach the use of phytosphingosine as a lipolytic agent. Like Jackson et al., Bombardelli do not teach or suggest the use of phytosphingosine as a slimming agent. As such, the subject matter of claims does have a structural difference over the cited art despite the Examiner's assertion to the contrary. The instant claims are directed to the new and unexpected use of phytosphingosine as a slimming agent, which was in no way identified in the cited art. Therefore, it is apparent that the unexpected new use discovered by the inventors is unobvious for one skilled in the art and support patentability of the composition.

The Examiner disagrees because first, the claims are drawn to a cosmetic composition containing phytosphingosine and at least one lipolytic agent not the phytosphingosine is a lipoytic agent. Second, since the claims are drawn to a

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composition, the use does not get patentable weight. In regards to claims having a structural difference over the cited art, the Examiner respectfully disagrees because although Jackson et al. or Bombardelli do not individually teach the specific combination of phytosphingosine and a lipolytic agent, the combined teachings of Jackson et al. and Bombardelli renders the composition obvious for reasons stated in the office action.

Claim 68 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,578,641 to Jackson et al, issued November 26, 1996, in view of U.S. Patent No. 5,679,358 to Bombardelli et al, issued October 21, 1997, and as applied to claims 67, 69 and 74-76 above, and further in view of WO 00/53568 to Streekstra et al, published September 14, 2000.

The Applicant argues that Jackson et al. and Bombardelli et al. are discussed above. Streekstra et al. has been discussed in previous responses. As the Jackson et al. and Bombardelli, Streekstra et al. do not teach or suggest the use of phytosphingosine as a slimming agent. Furthermore, claim 68, which depends from 67, relates to a hydrochloride salt of phytosphingosine and does not change the patentability which is already obtained for claim 67.

The Examiner disagrees for reasons stated above and as discussed in previous responses.

Claim 77 is rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 5,578,641 to Jackson et al. issued November 26, 1996 in view of U.S. Patent No. 5,679,358 to Bombardelli et al, issued October 21, 1997, as applied to claims 67, 69



and 74-76 above, and further in view of U.S. Patent No. 5,709,864 to Andre et al, issued January 20, 1998.

The Applicant argues that Jackson et al. and Bombardelli et al. are discussed above. Andre et al. has been discussed in previous responses. As such Andre et al. do not remedy the deficiencies of the primary references. Furthermore, claim 77, which depends from claim 75, which ultimately depends from claim 67, related to a composition wherein the adenylate cyclase enzyme activating agent is an extract of *Coleus forskohlii* and therefore does not change the patentability which is already obtained for claim 67.

The Examiner disagrees for reasons stated above and as discussed in previous responses. Additionally, the following teachings provide the teachings provide the limitation of claim 77: (1) Jackson et al. and Bombardelli et al. are applied as discussed for claims 67, 69 and 74-76 above, and teach a composition comprising phytosphingosine and an adenylate cyclase stimulator, and a method for applying the composition to the skin; (2) Bombardelli et al. furthermore teaches that the adenylate cyclase stimulator can be forskolin (see abstract, in particular); and (3) Andre et al. teaches that an extract of *Coleus forskohlii* contains forskoline (forskolin) and is known for its activity in stimulating adenylate cyclase (see column 5, lines 60-68, in particular.)

Claims 67, 69, 74 and 78-79 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 5,578,641 to Jackson et al. issued November 26, 1996 in view of U.S. Patent No. 5,709,864 to Andre et al, issued January 20, 1998.

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The Applicant argues that Jackson et al. and Andre et al. are discussed above. Jackson et al. and Andre et al. do not teach the combination of phytosphingosine with a lipolytic agent. The Examiner alleges that it would have been obvious to one of ordinary skill in the art to combine the extracts of Andre et al. in the wrinkle treating compositions of Jackson et al. However, Applicants respectfully submit that such motivation is possible only in light of impermissible hindsight and knowledge of the instantly claimed subject matter. It has not been properly shown how one would be motivated to combine two compositions designed to treat aging skin in order to arrive at a composition designed to reduce subcutaneous fat. As such, contrary to the Examiner's contention, the cited references do not teach compositions which are intended for the same purpose as the claimed methods and compositions, and upon this basis a prima facie case of obviousness has not been established. The claimed subject matter has a structural difference over the cited art because it is directed to the specific combination of phytosphingosine with a lipolytic agent, which is not recognized in the cited art.

The Examiner disagrees for reasons stated above and as discussed in previous responses in regards to the teachings of Jackson et al., Andre et al., and the claimed subject matter having a structural difference over the cited art. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In regards to the obviousness to combine the prior art references, such as a specific suggestion or teaching in the two references, the KSR forecloses the argument that a specific teaching, suggestion, or motivation is required to support a finding of obviousness. See the recent Board

decision EX parte Smith, --USPQ2d--, slip op. at 20, (Bd. Pat. App & Interf. June 25, 2007) (citing KSR, 82 USPQ2d at 1396) (available at <http://www.uspto.gov/web/offices/dcom/bpai/prec/fd071925.pdf>).

Claims 31-32, 34-35, 40-42 and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,679,358 to Bombardelli et al, issued October 21, 1997, in view of U.S. Patent No. 5,578,641 to Jackson et al, issued November 26, 1996.

The Applicant argues that Jackson et al. and Bombardelli et al. are discussed above, as well as, in previous responses. As stated previously through out this response, it is apparent that the unexpected new use discovered by the inventors is unobvious for one skilled in the art and support patentability of the method of use of the instant composition.

The Examiner disagrees because unlike the composition claims in which the use does not get patentable weight, the method claims receive patentable weight for obtaining a slimming effect on the human body. The combined teachings of Jackson et al. and Bombardelli et al. render the method claims obvious because one of ordinary skill in the art would have found it obvious to provide the phytosphingosine of Jackson et al. in the cellulitis and unesthetism treatment composition and method of Bombardelli et al, because Bombardelli et al. teaches treating cellulites and unesthetisms, such as those associated with skin aging, via topical application of the compositions, whereas Jackson et al. teaches that ceramide pathway intermediates such as phytosphingosine can be topically applied to reduce wrinkles associated with skin aging. Thus, one of ordinary skill in the art would have been motivated to provide the skin-aging and wrinkle

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treating phytosphingosine ingredient of Jackson et al, in the cellulites and skin aging unestetism treating composition and method of Bombardelli et al, with the expectation of providing a composition and method that treats skin unestetisms such as cellulitis and other signs of the early aging of skin such as skin wrinkles.

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,679,358 to Bombardelli et al, issued October 21, 1997, in view of U.S. Patent No. 5,578,641 to Jackson et al, issued November 26, 1996, as applied to claims 31-32, 34-35, 40-42 and 84 above, and further in view of WO 00/53568 to Streekstra et al, published September 14, 2000.

The Applicant argues that each of the cited references is discussed above and in previous responses. None of the cited references teach or suggest the use of phytoshpingosine as a slimming agent. Furthermore, claim 31, which depends from claim 33, relates to a hydrochloride salt of phytosphingosine and does not change the patentability which is already obtained for claim 31.

The Examiner disagrees for reasons stated above and as discussed in previous responses in regards to the teachings of Jackson et al., Bombardelli et al., and Streekstra et al. Particularly, Streekstra et al. provides the teaching that forming the salt of sphingoid bases, such as the hydrochloric acid salt phytosphingosine, provides a sphingoid compound having better solubility in topical formulations containing water than their free base counterparts. Thus, the combined teachings of the cited references teach the limitation of claim 33.

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Claims 43-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,679,358 to Bombardelli et al, issued October 21, 1997, in view of U.S. Patent No. 5,578,641 to Jackson et al, issued November 26, 1996, as applied to claims 31-32, 34-35, 40-42 and 84 above, in view of U.S. Patent No. 5,709,864 to Andre et al, issued January 20, 1998.

The Applicant argues that each of the cited references is discussed above and in previous responses. Andre et al. does not remedy the deficiencies of the primary references. Furthermore, claims 43-44, which depend indirectly from claim 31, relate to methods of use of a composition where in the adenylate cyclase enzyme activating agent is an extract of *Coleus forskohlii* or *Tephrosia purpurea* and therefore does not change the patentability which is already obtained for claim 31.

The Examiner disagrees because for reasons stated above and as discussed in previous responses in regards to the teachings of Jackson et al., Bombardelli et al., and Andre et al. Particularly, one of ordinary skill in the art at the time the invention was known would have found it obvious to provide the *Coleus forskohlii* extract or *Tephrosia purpurea* extracts of Andre et al. in the phytosphingosine and adenylate cyclase stimulator composition and method of Bombardelli et al. and Jackson et al, because Bombardelli et al. and Jackson et al. teach that an adenylate cyclase stimulator such as forskolin can be provided, and Andre et al. teaches that an extract of *Coleus forskohlii* provides the forskolin adenylate cyclase stimulator, and that *Tephrosia pupurea* extract also provides an adenylate cyclase activating agent. Thus, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the extracts of Andre et al. in the composition and/or method of Bombardelli et al. and

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Jackson et al, with the expectation of providing a suitable forskolin containing adenylate cyclase stimulator in the composition and method. Accordingly, claims 43-44 are obvious over the combined teachings of Bombardelli et al, Jackson et al, and Andre et al.

### ***Conclusion***

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

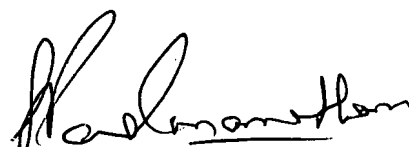
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kendra D. Carter whose telephone number is (571) 272-9034. The examiner can normally be reached on 8:30 am - 5:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KDC



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